

**Submitted by:** MIE America Inc.  
420 Benett Road  
Elk Grove Village, IL 60007

**Telephone:** 847 981 6100

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**Contact Person:** Kay Warren

**Date Summary prepared** 06/24/2005

**Trade Name of Devices** MIE – Gamma Camera Systems

**Common Name** Gamma Camera Systems

**Classification** Class I

MIE - BODYSCAN SCINTRON  
MIE - SD-X 37 SCINTRON  
MIE - LFOV SCINTRON

Class II

MIE - ORBITER SCINTRON  
MIE - DIACAM SCINTRON  
MIE - MULTISPECT 2 SCINTRON  
MIE - MULTISPECT 3 SCINTRON  
MIE - GE-XR/T SCINTRON  
MIE - GE-AC/T) SCINTRON

**Substantial Equivalence:****MiE Gamma Camera System****Substantial equivalent system**

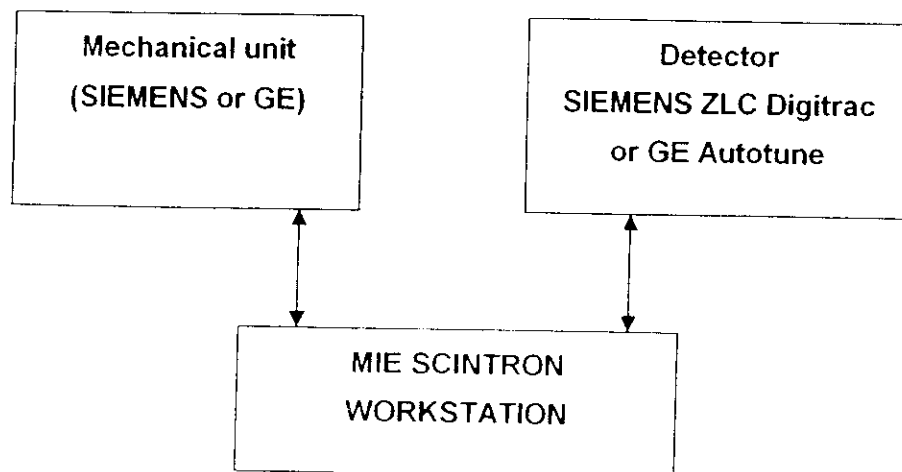
MiE – ORBITER-SCINTRON	SIEMENS ORBITER II CCI / Spect
MiE – DIACAM- SCINTRON	SIEMENS DIACAM GAMMA CAMERA
MiE – MULTISPECT 2 – SCINTRON	SIEMENS MULTISPECT™ 2 DUAL DETECTOR CAMERA SYSTEM
MiE – MULTISPECT 3 – SCINTRON	SIEMENS MULTISPECT™ 3 TRIPLE DETECTOR CAMERA SYSTEM
MiE – BODYSCAN- SCINTRON	SIEMENS BODYSCAN
MiE - LFOV – SCINTRON	BASICAM Counter balanced
MiE – 9SD-X 37 – SCINTRON	BASICAM Counter balanced
MiE – GE-XR/T – SCINTRON	GE Starcam 4000
MiE – GE-AC/T – SCINTRON	GE Maxicamera 400 ac

**Intended Use:**

The MiE - Gamma Camera Systems for nuclear medicine, used to perform static, dynamic and gated studies, as well as spect or planar procedure, on standing, seated or recumbent patients

**A Description of the device:**

All MiE remanufactured Gamma Camera System have 3 functional units equivalent to the Siemens or GE Gamma Camera Systems.



The modification to the SIEMENS- or GE-Gamma Camera System consisted of removal of certain low voltage circuit boards in the gamma Camera and the gantry portions of the Siemens – or GE Gamma Camera System and installing proprietary low voltage circuit board that allow the use of our SCINTRON Computer and its software.

### **Detecting units**

All MIE Gamma Camera Systems consist of the same detector unit that is in use in the Siemens- or GE Gamma Camera System, and we claim substantial equivalence in comparison to that detector unit.

### **Mechanical units**

The mechanical units (camera head with its supporting beam) hold the detector and make sure it can be moved around or along the patient for the optimal diagnostic procedure.

For more details see the descriptions of the devices in Annex 2.

There are no differences between the mechanical units from the SIEMENS or GE Gamma Cameras and the MIE remanufactured Gamma Cameras.

### **SCINTRON Workstation**

The only difference to the basic SIEMENS or GE Gamma Camera system consists in our own imaging and processing software SCINTRON (already cleared by the FDA, K953193).

The technical data's and specifications in Annex 1 show that the MIE remanufactured Gamma Camera System achieve the same technical data's as the basic SIEMENS or GE Gamma Camera systems.

## **B Substantial Equivalence Summary**

The MIE remanufactured Gamma Camera Systems have the same indications for use and target population as the predicate devices. There are no differences regarding the diagnostic effect. The MIE remanufactured devices have the same technological characteristics as the basic SIEMENS or GE Devices. For all technical data performance data are provided to assure equivalence.

## **C Technical Characteristics**

The technological characteristics are the same as those of the predicate devices.

**D Testing**

Performance testing addressed the following issues:

- Electrical safety
- Electromagnetic compatibility and
- NEMA Performance standards

**E Conclusions**

This pre-market notification has demonstrated Substantial Equivalence between the MIE remanufactured Gamma Camera Systems and the basic SIEMENS or GE Gamma Camera System as defined and understood in Sections 513 (f) (1) and 513 (i) (1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

**510 (k) number:**

**Device Name:** MIE Gamma Camera System

**Indication for Use:** The MIE - Gamma Camera Systems for nuclear medicine, used to perform static, dynamic and gated studies, as well as spect or planar procedure, on standing, seated or recumbent patients



JAN 27 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kay Warren  
Official Correspondent  
MIE America, Inc.  
420 Benett Road  
ELK GROVE VILLAGE IL 60007

Re: K053086  
Trade/Device Name: MiE-Gamma Camera Systems  
Regulation Number: 21 CFR 892.1100  
Regulation Name: Scintillation (gamma) camera  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission computed  
tomography system  
Regulatory Class: I and II  
Product Code: KPS and IYX  
Dated: March 17, 2005  
Received: November 15, 2005

Dear Ms. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known):

K 053086

Device Name:

MiE - Gamma Camera Systems MiE - Gamma Camera Systems

Indications For Use:

The MIE - Gamma Camera Systems for nuclear medicine, are used to perform static, dynamic and gated studies, as well as spect or planar procedure, on standing, seated or recumbent patients

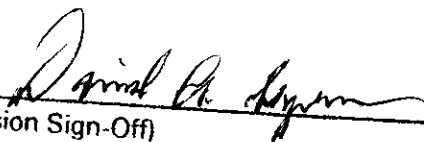
Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K053086